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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,772	02/22/2002	Janet K. Yamamoto	UF-267XC1	1105

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,772

Applicant(s)

YAMAMOTO ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/19/2004, 09/10/2004, and 10/06/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 36-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-28 and 36-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Serial No.: 10/080,772
Applicants: Yamamoto, J. K., et al.

Docket No.: UF-267XC1
Filing Date: 02/22/2002

Detailed Office Action

Status of the Claims

Applicants are advised that the office action mailed 16 December, 2003, has been vacated in favor of the following office action. Acknowledgement is hereby made of receipt and entry of the communications filed 19 March, 2004 (a copy of which was again provided on 10 September, 2004) and 06 October, 2005. The claim amendments set forth in the former communication have been entered. Thus, claims 1-28 and 36-46 are pending in the instant application. Applicants' arguments/comments have been considered to the extent they are relevant to the instant action.

37 C.F.R. § 1.142

Applicants are reminded that pursuant to 37 C.F.R. § 1.142(a) if two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-14, drawn to **methods of inducing an immune response** to feline immunodeficiency virus (FIV) or human immunodeficiency virus (HIV) in a human or non-feline

animal by administering an FIV immunogen, classified in class 424, subclass 208.1.

- b. Group II, claim(s) 15-28, drawn to a **method of treating or preventing FIV infection** in a human or non-feline animal by administering an FIV immunogen and alternatively an antiviral, classified in class 424, subclass 188.1 and class 514, subclass 1.
- c. Group III, claim(s) 36-39, drawn to an isolated cross-reactive HIV/FIV-specific **antibody**, classified in class 530, subclasses 387.1, 388.35, and 389.4.
- d. Group IV, claim(s) 40 and 41, drawn to a **method of detecting FIV-specific antibodies**, classified in class 435, subclasses 5 and 7.1.
- e. Group V, claim(s) 40 and 42, drawn to a **method of detecting FIV nucleotide sequences**, classified in class 435, subclasses 5 and 6.
- f. Group VI, claim(s) 43 and 44, drawn to **nucleic acids** encoding HIV and FIV proteins, classified in class 536, subclass 23.72.
- g. Group VII, claim(s) 45 and 46, drawn to **proteins** obtained from HIV or FIV, classified in class 424, subclass 202.1.

The inventions are distinct, each from the other because of the following reasons:

Unrelated Inventions

Inventions III, VI, and VII are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a structurally (e.g., antibody, nucleic acid, protein) and functionally different product with disparate physicochemical, immunological, and virological properties. Separate searches will also clearly be required for each group.

Therefore, each product is clearly directed toward a different inventive entity.

Inventions I, II, IV, and V are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different methodology (e.g., induction of an immune response, prevention of viral infection, detection of antibodies, detection of nucleic acids) that accomplishes different scientific objectives and employs different scientific reagents and protocols. Separate searches will also be required for each invention. Therefore, each group is clearly directed toward a different inventive concept.

Inventions I and I/II/IV/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of groups I, II, IV, and V neither require nor utilize the product of group I.

Inventions VI/VII and IV/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the methodologies of groups IV and V neither require nor utilize the products of groups VI and VII.

Product and Process of Using

Inventions VI/VII and I/II are related as product and process of

use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of group VI can be employed in a number of materially different processes such as detecting methods to identify HIV/FIV in biological samples. Moreover, the proteins of group VII can be employed in a number of materially different processes such as detection methods to identify HIV/FIV-specific antibodies or in affinity purification protocols to isolate binding partners.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

37 C.F.R. § 1.48(b)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Claim Rejoinder (M.P.E.P. § 821.04)

Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or otherwise include **all** the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See *AGuidance on Treatment of Product and Process Claims* in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy,

Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so will result in a loss of the right to rejoinder. Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

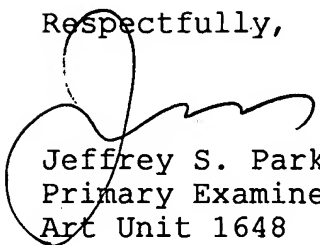
Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access

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to the Private PAIR system, contact the Electronic Business Center
(EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

11 November, 2006